4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-1600]

Gabriel J. Letizia, Jr.: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Gabriel J. Letizia, Jr. from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Letizia was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Letizia was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why he should not be debarred within the timeframe prescribed by regulation. Mr. Letizia has not responded to the notice. Mr. Letizia's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for special termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On May 18, 2022, Mr. Letizia was convicted in the U.S. District Court for the Southern District of New York, of one felony count of conspiracy to commit wire fraud in violation of 18 U.S.C. 371, and two misdemeanor counts of misbranding in violation of 21 U.S.C. 331(a) and 333(a)(1). FDA's finding that debarment is appropriate is based on the felony conviction referenced herein.

The factual basis for this conviction is as follows: As contained in the Superseding Information in Mr. Letizia's case, filed May 4, 2021, and from the transcript of his guilty plea hearing, filed on May 26, 2021, Mr. Letizia was the owner and executive director of AMA Laboratories (AMA), a consumer product testing company in Rockland County, New York. Mr. Letizia began operating AMA in the early 1980s and became its sole owner in approximately 2003. Mr. Letizia falsely used the title "Dr." in correspondence, falsely representing to customers that he held a Ph.D. AMA purported to test the safety and efficacy of cosmetics, sunscreens, and other products on specified numbers of volunteer panelists for consumer products companies. AMA's customers would use the test results to support their claims that their products were safe, effective, hypoallergenic, or provided a certain sun protection factor (SPF), including after exposure to water. AMA customers that manufactured sunscreens used the test results to comply with FDA regulations requiring sunscreen manufacturers to have their products tested and to maintain the test results for possible review by the FDA.

From 1987 to April 2017, Mr. Letizia and AMA personnel operating at Mr. Letizia's direction, defrauded AMA's customers of more than $46 million by testing products on materially lower numbers of panelists than the numbers specified and paid for by AMA's

customers. At Mr. Letizia's direction, AMA personnel rarely tested products on the number of panelists requested by AMA's customers and for which they had paid. AMA's fees for tests were based, in part, on the number of panelists that were to participate in the study. However, at Mr. Letizia's direction AMA sent its customers fraudulent test results, via interstate email and facsimile communications, in which AMA personnel included fictitious data for "phantom" panelists who had not actually participated in the tests. At Mr. Letizia's direction, AMA employees had panelists who agreed to partake in studies at AMA fill out consent forms and other paperwork as if they would be participating in all of the studies that were being performed at AMA at that time. These panelists were then used as "phantom" panelists in other studies, and their consent forms for those studies would falsely make it appear to those who might audit AMA's files, including FDA investigators and AMA's customers, that the panelists had participated in studies when, in fact, they had not. In addition, AMA customers who paid for AMA to test their sunscreen products relied on the reliability of AMA's test results for purposes of accurately and lawfully labeling the SPF level of the sunscreen products those customers intended to sell. Mr. Letizia knowingly caused AMA employees to send false reports to AMA's customers in that testing had not been performed on the whole panel as requested and paid for by AMA's customers. In so doing, Mr. Letizia knowingly caused AMA's customers to market and sell to consumers in the United States and elsewhere, sunscreen, with labels that failed to reveal material facts in that the labels on these products stated that the SPF level of the sunscreen was 50 with no indication on that label that the laboratory testing of the panel paid for by AMA customers had not been performed.

In addition, at Mr. Letizia's direction, AMA personnel routinely falsified test results relating to AMA's customers' products, which included suppressing reports of adverse reactions and deviating from testing protocols. AMA personnel reported adverse reactions to customers only in extreme cases and often offered to retest the product and, in some cases, change the test procedure with the hope of reducing the number of reported negative reactions. AMA personnel

also falsified data to accord with prior results from smaller "screener" study results or customer expectations.

Based on this conviction, FDA sent Mr. Letizia by certified mail on September 12, 2022, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Letizia was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Letizia an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to file a timely request for a hearing would constitute an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Letizia received the proposal on September 16, 2022. He did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Letizia has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Letizia is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see DATES) (see sections 306(a)(2)(B) and (c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Letizia during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Letizia provides services in any capacity to a person with an

approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Letizia during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a "drug product" is defined as a "drug subject to regulation under section 505, 512, or 802 of this Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]" (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Letizia for special termination of debarment under section 306(d)(4) of the FD&C Act) should be identified with Docket No. FDA-2022-N-1600 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at https://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: January 11, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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